
CANCER FACTS

National Cancer Institute • National Institutes of Health

Selenium and Vitamin E Cancer Prevention Trial (SELECT): Questions and Answers

1. What is SELECT?

SELECT stands for the Selenium and Vitamin E Cancer Prevention Trial, which is a clinical trial to see if one or both of these dietary supplements prevent prostate cancer in men. It is funded by the National Cancer Institute (NCI) and is being coordinated by the Southwest Oncology Group (SWOG), an international network of research institutions that receives NCI funding. Enrollment will last for approximately 5 years, and the study will continue for 7 years after the last man has enrolled, meaning that each man's participation will last 7 to 12 years, depending on when he joins the study. More than 400 sites in the United States, Puerto Rico, and Canada are taking part in the study. Over 32,000 men will participate in SELECT.

2. What are a man's chances of developing prostate cancer?

After skin cancer, prostate cancer is the most common type of cancer in men in the United States. There will be an estimated 198,100 new cases of prostate cancer and 31,500 deaths from this disease in the United States in the year 2001.

All men are at risk, but those at highest risk fall into one or more of the following categories: age 55 or older; black; or have a father or brother with prostate cancer.

3. What is selenium? Why study it for prostate cancer prevention?

Our bodies need selenium, a nonmetallic trace element that we get from water and food—especially seafood, meats, and Brazil nuts. Selenium is an antioxidant that is believed to help control cell damage that can lead to cancer.

In a 1996 study of 1,000 men and women, those men who took selenium to prevent nonmelanoma skin cancer received no benefit from selenium in preventing skin cancer. However, there was about a 60 percent reduction in the number of new cases of prostate cancer in those men taking selenium than in those men who did not, which is one of the reasons why this substance is being studied in SELECT.



4. What is vitamin E? Why study it for prostate cancer prevention?

We get vitamin E (a naturally occurring nutrient) in a wide range of foods, especially vegetables, vegetable oils, nuts, and egg yolks. Vitamin E, like selenium, is an antioxidant, which is believed to help control cell damage that can lead to cancer.

In a 1998 study of 29,000 male smokers in Finland, men who took vitamin E to prevent lung cancer had 32 percent fewer new cases of prostate cancer than men who took the placebo. Some men also took beta carotene, but neither substance helped prevent lung cancer.

5. What do researchers hope to learn from SELECT?

SELECT is the first study to look directly at the effects of selenium and vitamin E on the risk of prostate cancer. This study is being done to find out if selenium, vitamin E, or both prevent prostate cancer.

A large trial of selenium and vitamin E is needed to substantiate earlier, separate findings where prostate cancer was not the primary outcome. Although two earlier studies suggested that these two supplements may prevent prostate cancer, this cancer was not the focus of those studies. The primary goal of SELECT is to assess the effect of these substances on the number of new cases of prostate cancer diagnosed during routine clinical practice. Other objectives are to assess the impact of selenium and vitamin E on the incidence of lung and colon cancer, as well as on survival. SELECT will study the molecular genetics of cancer risk and associations between diet and cancer. Additionally, SELECT will also examine quality of life.

6. Who is eligible to participate in SELECT? Are there restrictions on eligibility?

Many diseases, including prostate cancer, occur more frequently in older persons. The risk of developing prostate cancer increases with age. About 98 percent of prostate cancer cases occur in men ages 55 and older.

Black men must be age 50 or older to participate, and men of other races and ethnicities must be 55 or older. The age for eligibility is lower for black men because they get the disease at an earlier age. In addition, black men in the United States have the highest incidence of prostate cancer in the world. Thus, the SELECT age requirement ensures that men who are at risk for the disease are targeted.

Men who have taken, or are taking, vitamin E and/or selenium on their own must stop using these supplements and any multivitamins and use only what is provided by SELECT. These supplements will be provided to participants free of charge, including a multivitamin that does not contain vitamin E or selenium. Past use of these supplements does not disqualify men from joining SELECT.

Participants must have no history of prostate cancer. Men who join SELECT also must not have had any other cancer, except nonmelanoma skin cancer, in the last 5 years. They must be in generally good health. In addition, many of the 18,000 men who enrolled in another prevention study sponsored by NCI and run by SWOG, known as the Prostate Cancer Prevention Trial (PCPT), will be eligible to participate in SELECT once they have completed the PCPT by having had their end-of-study biopsy and exited the PCPT trial with no evidence of prostate cancer.

Some study sites are located at Veterans Administration hospitals run by the Department of Veterans Affairs. To enroll at these sites, men must be veterans, although they do not have to receive their routine medical care at that hospital.

7. Can men with benign prostatic hyperplasia (BPH) join SELECT?

Men with BPH, an abnormal growth of benign prostate cells, can join SELECT because BPH is not a cancerous condition. In BPH, the prostate grows larger and presses against the urethra and bladder, interfering with the normal flow of urine. More than half of the men in the United States between the ages of 60 and 70, and as many as 90 percent of men between the ages of 70 and 90 have symptoms of BPH.

BPH can be treated with four different FDA-approved drugs: finasteride (Proscar®), terazosin (Hytrin®), doxazosin (Cardura®), and tamsulosin (Flomax®). Most men taking any one of these drugs for this purpose will be eligible to participate in SELECT.

8. What tests are used to determine eligibility for SELECT?

Tests include a digital rectal examination (DRE) and a prostate-specific antigen (PSA) test. During a DRE, a doctor inserts a gloved finger into the rectum and feels the prostate gland through the rectal wall to check for bumps or abnormal areas. The PSA test measures the level of PSA (a protein produced by the cells of the prostate gland) in the blood. PSA levels can rise due to cancer or benign (not cancerous) conditions. Doctors often use the PSA test and DRE as prostate cancer screening tests in men who have no symptoms of the disease.

To be eligible for the SELECT trial, participants must have a DRE that indicates no signs of prostate cancer and a total PSA level less than or equal to 4.0 ng/ml.

While enrolled in SELECT, DREs and PSA tests are suggested, but not required, on an annual basis throughout the course of the study.

9. Who pays for these tests?

Physician, medical examination, and general clinic costs, including DREs, are charged to the participant in the same way as if he were not part of the trial. However, the costs of these tests may be covered by a participant's health insurance. Financial assistance may be available for some men. SELECT will, however, pay for followup PSA tests. Men

with questions about insurance coverage or reimbursement should check with their local SELECT site.

10. Who will get which supplement?

Men who participate in this study will take two capsules a day. Participants are randomized to four possible choices:

- selenium and vitamin E
- selenium and a placebo
- vitamin E and a placebo
- two placebos

There are two placebos used in the trial: one looks and tastes like a selenium capsule; the other looks and tastes like a vitamin E capsule. Each placebo contains only inactive ingredients. Neither the participants nor the researchers will know who is receiving the selenium and vitamin E, or the placebos, until the end of the study.

Roche Vitamins, Inc., Parsippany, New Jersey, is donating bulk vitamin E and vitamin E placebo; Nutricia Manufacturing USA, Inc., Greenville, South Carolina, is encapsulating the vitamin E and vitamin E placebo at no charge; and Sabinsa Corporation, Piscataway, New Jersey, is providing selenium and selenium placebo, both of which are already encapsulated, at manufacturing cost.

11. How much selenium and vitamin E are being used in the study? What risks might be involved?

The amount of selenium (provided as l-selenomethionine) is 200 micrograms (μg) daily. The amount of vitamin E (provided as dl-alpha-tocopherol acetate) is 400 milligrams (mg), which is equivalent to 400 International Units (IU), per day. Previous studies have shown that these amounts are safe in healthy men.

The 200 μg per day dose of selenium would have to be increased to more than 2,400 μg per day of selenium for it to be considered “too much.” The 400 mg dose of vitamin E is safe, but can thin blood somewhat. Men with uncontrolled high blood pressure may have an increased risk of stroke if they take 400 mg of vitamin E and, therefore, cannot take part in this study.

12. What other requirements are there for SELECT participants?

Upon enrollment, men will be asked to have toenail clippings collected to assess selenium levels in the body since selenium concentrates in fingernails and toenails. Toenails are chosen over fingernails because they take longer to grow and thus contain more history of someone’s selenium intake. Blood samples will also be collected upon enrollment to assess levels of vitamin E.

Men will fill out a questionnaire on their diet and past supplement use upon enrolling. There will also be an annual questionnaire that asks for updates of some of this information. Men do not have to change their diets during this study. Each man will be offered a free supply of a special daily multivitamin, manufactured by BioAdvantex Pharma, Inc., Mississauga, Ontario, Canada, that contains no selenium or vitamin E, to take as he chooses. Vitamin E, selenium, and placebo capsules are also provided free of charge to enrollees for the duration of the study.

Participants will be asked to return to the study site every 6 months to pick up a 6-month supply of capsules.

13. Why should men participate in SELECT?

Men involved in SELECT will be partners in medical research that may decrease their chances of getting prostate cancer. Information learned from this study may also help future generations of men avoid this cancer.

14. What happens if a participant develops prostate cancer while involved in SELECT?

If prostate cancer is found, the participant will be referred for treatment, will stop taking the study supplements, and will continue to be followed by the SELECT study staff, although less frequently.

Costs for diagnosis and treatment of prostate problems, prostate cancer, or other medical conditions during the study will be charged to the participant in the same way as if he were not part of the trial. A participant's insurance will pay for diagnosis and treatment according to the plan's policies. If the participant has no insurance, social services may be available at the local level to cover costs for diagnosis and treatment.

15. What other clinical trials are under way for prostate cancer prevention?

In addition to SELECT and the Prostate Cancer Prevention Trial (PCPT), smaller trials are also being conducted with a variety of agents, including a vitamin D analog; eflornithine (a compound called DFMO); flutamide (Eulexin®) and bicalutamide (Casodex®), both antiandrogens; soy isoflavones; lycopene (a plant pigment common in tomatoes); celecoxib (a COX-2 inhibitor); and combinations of agents.

16. How can a potential participant or a physician get more information about SELECT?

In the United States and Puerto Rico, call the National Cancer Institute's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615 for information in English or Spanish. In Canada, call the Canadian Cancer Society's Cancer Information Service at 1-888-939-3333 for information in English or French.

The following Web sites can also provide additional information:

- For the SELECT Web site, hosted by SWOG, choose the SELECT option at **<http://swog.org>**
- NCI information on SELECT: **<http://cancer.gov/select>**

SELECT Audio-Visual Materials

- To listen to a radio news story about SELECT, visit **<http://www.radiospace.com/nihhome.htm>**. Click on July 24, 2001, story on NCI's SELECT trial launch.
- To view an online copy of the Video News Release about SELECT, visit **<http://www.streamonsite.com/hendrick/nci.ram>**
- To view an image of the crystalline structure of vitamin E, go to: **<http://newscenter.cancer.gov/pressreleases/SELECTcrystal.gif>**
- To view an image of the chemical structure of vitamin E, go to: **<http://newscenter.cancer.gov/pressreleases/SELECTchemistry.gif>**
- To view an image of the prostate, go to: **<http://newscenter.cancer.gov/pressreleases/SELECTprostate.gif>**
- To view an image of vitamin E capsules, go to: **<http://newscenter.cancer.gov/pressreleases/SELECTVitEpill.gif>**
- To view an image of selenium capsules, go to: **<http://newscenter.cancer.gov/pressreleases/SELECTselenium.gif>**
- To view an image of selenium and vitamin E capsules, go to: **<http://newscenter.cancer.gov/pressreleases/SELECTbothpills.gif>**

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Sources of National Cancer Institute Information

Cancer Information Service

Toll-free: 1-800-4-CANCER (1-800-422-6237)

TTY (for deaf and hard of hearing callers): 1-800-332-8615

NCI Online

Internet

Use <http://cancer.gov> to reach NCI's Web site.

CancerMail Service

To obtain a contents list, send e-mail to cancermail@cips.nci.nih.gov with the word "help" in the body of the message.

CancerFax® fax on demand service

Dial 1-800-624-2511 or 301-402-5874 and follow the voice-prompt instructions.

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